

REMARKS

Status Summary

Claims 1, 3-8 and 15-39 are now pending in the subject U.S. patent application. Claims 17-20 and 22-36 have been withdrawn pursuant to a Restriction/Election Requirement issued by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Accordingly, claims 1, 3-8, 15, 16, 21 and 37-39 have been examined by the Patent Office. Claims 1, 3-8, 15, 16, 21 and 37-39 presently stand rejected.

Claims 1, 3-8, 15, 16 and 21 have been rejected under 35 U.S.C. §102(a/e) upon the contention that the claims are anticipated by PCT Patent Application Publication WO 02/26192 to Van Meir et al. (hereinafter "Van Meir et al.").

Claim 37 has been rejected under 35 U.S.C. §103(a) upon the contention that the claim is obvious in view of Van Meir et al.

Claims 38 and 39 have been rejected under 35 U.S.C. §103(a) upon the contention that the claims are obvious over Van Meir et al. in view of Shibata et al. (*International Journal of Radiation Oncology Biology Physics*, 1998, 42(4): 913-916; hereinafter "Shibata et al.").

Reconsideration of the application based on the amendments and arguments set forth herein is respectfully requested.

*Response to the Rejection of Claims under 35 U.S.C. § 102(a/e)*

Claims 1, 3-8, 15, 16 and 21 have been rejected under 35 U.S.C. §102(a/e) upon the contention that the claims are anticipated by Van Meir et al. The Patent Office contends that Van Meir et al. teaches each and every element of claims 1, 3-8, 15, 16 and 21.

The rejection as it appeared in the previous Official Action was traversed by applicants on the ground, among others, that the method of Van Meir et al. does not disclose an adenovirus vector comprising an adenovirus gene selected from the group consisting of an E1B gene, an E2A gene, an E2B gene, and an E4 gene, wherein the adenovirus gene is under the transcriptional control of a transcriptional regulatory element (TRE) comprising a minimal promoter and a hypoxia responsive element (HRE). The Patent Office asserts in the instant Official Action that these arguments are not found persuasive and refers to page 34, lines 1-2 of Van Meir et al., which recites "Recombinant viruses were able to express constitutively (Ad-CMV-E1) or conditionally (HYPR-Ad1) E1A and E1B gene products.". See, pages 4-5 of the Official Action. Accordingly, the Patent Office asserts that this disclosure in Van Meir et al. teaches an adenovirus vector comprising two adenovirus genes under the transcriptional control of a TRE, including an E1B gene.

After careful consideration of the instant rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

In the instant Official Action the Patent Office maintains the assertion that Van Meir et al. teaches each and every element of the rejected claims based on what applicants believe to be a selective reading of Van Meir et al. In response to the Patent Office's referral to page 34, lines 1-2, of Van Meir et al. in the previous Official Action, applicants directed the Patent Office's attention to the preceding paragraph at page 33, lines 25-29, of Van Meir et al. However, the Patent Office appears to have failed to address this in the instant Official Action. As such, applicants again respectfully direct the Patent Office's attention to page 33, lines 25-29, of Van Meir et al., which states the following:

E1A is activated by hypoxia in HYPR-Ad1. E1A is known to activate the expression of other viral promoters including early E1B gene regulation. This explains the increased expression of E1B gene products under hypoxia. Late E1B gene regulation involves other factors and may explain the increased expression of E1B21K under normoxia at 2-3 days post-infection.

(emphasis added).

As such, in contrast to the apparent assertion by the Patent Office, Van Meir et al. does not teach an adenovirus vector comprising two adenovirus genes, wherein each is under the transcriptional control of a TRE. In marked contrast, Van Meir et al., at best, discloses an adenovirus vector with an E1B gene that is regulated by E1A. E1B is not believed to be under the transcriptional control of a TRE. As such, applicants respectfully submit that Van Meir et al. fails to disclose an adenovirus vector comprising two adenovirus genes and a transgene, wherein both adenovirus genes and the transgene are each under the transcriptional control of a TRE, as

recited in claim 3. Furthermore, applicants respectfully submit that Van Meir et al. does not teach an adenovirus vector comprising an adenovirus gene and transgene, wherein the adenovirus gene selected from E1B, E2A, E2B and E4 is under the transcriptional control of a TRE, as recited in present claim 1. Thus, applicants respectfully submit that Van Meir et al. fails to support a rejection of claim 1 under 35 U.S.C. §102(a/e).

Accordingly, applicants respectfully submit that Van Meir et al. does not teach each and every element of independent claim 1, and therefore fails to support a rejection of claim 1 under 35 U.S.C. §102(a/e). Accordingly, applicants respectfully request that the instant rejection be withdrawn at this time. A Notice of Allowance directed to claim 1 is also respectfully requested.

Applicants further submit that claims 3-8, 15, 16 and 21 depend either directly or indirectly from independent claim 1. Accordingly, the instant 35 U.S.C. §102(a/e) rejection of these claims has also been addressed. Thus, applicants respectfully request that the instant rejection be withdrawn at this time. A Notice of Allowance directed to these claims is also respectfully requested.

*Response to the Rejection of Claim 37 under 35 U.S.C. § 103(a)*

Claim 37 has been rejected under 35 U.S.C. §103(a) upon the contention that the claim is obvious in view of Van Meir et al. The Patent Office contends that Van Meir et al. teaches each and every element of claim 37 except that the adenovirus genes E2A, E2B, or E4 can be among those genes regulated by hypoxia-responsive

promoters. However, the Patent Office contends that it would have been obvious to one of ordinary skill in the art to modify the teachings of Van Meir et al. to construct an adenovirus comprising the two adenovirus genes, E1B and E4, each under the control of a hypoxia-responsive promoter. As such, the Patent Office contends that claim 37 is *prima facie* obvious in view of Van Meir et al.

After careful consideration of the instant rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

Applicants respectfully submit that the discussion hereinabove regarding the deficiencies of the teachings of Van Meir et al. with regard to the rejection of claims 1, 3-8, 15, 16 and 21 under 35 U.S.C. §102(a/e) equally applies to the instant rejection of claim 37 under 35 U.S.C. §103(a). In particular, applicants respectfully submit that for at least the reasons noted hereinabove Van Meir et al. fails to disclose an adenovirus vector comprising two adenovirus genes and a transgene, wherein both adenovirus genes and the transgene are each under the transcriptional control of a TRE, as recited in claim 37. As such, applicants respectfully submit that it would not have been obvious to modify the teachings of Van Meir et al. as suggested by the Patent Office.

Accordingly, the instant 35 U.S.C. §103(a) rejection of claim 37 has been addressed. Thus, applicants respectfully request that the instant rejection be withdrawn at this time. A Notice of Allowance directed to claim 37 is also respectfully requested.

Response to the Rejection of Claims 38 and 39 under 35 U.S.C. § 103(a)

Claims 38 and 39 have been rejected under 35 U.S.C. §103(a) upon the contention that the claims are obvious over Van Meir et al. in view of Shibata et al. (*International Journal of Radiation Oncology Biology Physics*, 1998, 42(4): 913-916; hereinafter "Shibata et al."). Regarding claim 38, the Patent Office contends that Van Meir et al. teaches each and every element of the claims except that the minimal promoters can be selected from the group consisting of human  $\beta$ -actin minimal promoter, the human EF2 minimal promoter, and the adenovirus E1B minimal promoter. Likewise, the Patent Office contends that Van Meir et al. teaches each and every element of claim 39 except that the adenovirus genes E2A, E2B, or E4 can be among those genes regulated by hypoxia-responsive motors. However, in both instances, the Patent Office contends that Shibata et al. compensates for these deficiencies.

After careful consideration of the instant rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

Applicants respectfully submit that the discussions hereinabove regarding the deficiencies of the teachings of Van Meir et al. with regard to claims 1, 3-8, 15, 16, 21 and 37 equally apply to the instant rejection of claims 38 and 39 under 35 U.S.C. §103(a). Further, applicants respectfully submit that Shibata et al. fails to compensate for these deficiencies in Van Meir et al. As such, applicants respectfully submit that the proposed combination of Van Meir et al. and Shibata et al. is not

believed to render claims 38 and 39 obvious.

Accordingly, the instant 35 U.S.C. §103(a) rejection of claims 38 and 39 has been addressed. Thus, applicants respectfully request that the instant rejection be withdrawn at this time. A Notice of Allowance directed to claims 38 and 39 is also respectfully requested.

#### CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any additional fees or credit any overpayments associated with the filing of this correspondence to Deposit Account No. 50-0426.

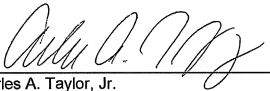
Respectfully submitted,

JENKINS, WILSON, TAYLOR & HUNT, P.A.

Date:

07/06/2009

By:



Arles A. Taylor, Jr.  
Registration No. 39,395  
Customer No. 25297  
(919) 493-8000

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